UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/582,295 | 06/18/2007 | Williams Vivienne | 1817-0172PUS1 | 2932 |

2292 7590 02/19/2010

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

| EXAMINER | |
|---|---|
| RAMDHANIE, BOBBY | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1797 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 02/19/2010 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/582,295 | VIVIENNE ET AL. | |
| | Examiner | Art Unit | |
| | BOBBY RAMDHANIE | 1797 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *18 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/12/2006, 04/10/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Oath/Declaration*

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The full name of each inventor (family name and at least one given name together with any initial) has not been set forth.

Applicants' Specification on Page 1 lines 11-20, states that,

"Various biochip assemblies and, in particular, methods for using such biochip assemblies have been previously described in our co-pending PCT Patent Application Nos. IE02/00107 (WO 03/060056) and No. 02/00060 (WO 02/090771) and European Patent Specification Nos. EP 1252929 and EP 1221617."

All of the references above state that one of the inventors is Igor Shvets. The instant application states that at least one of the inventors is Igor Schvets. It is unclear if this is the same inventor as disclosed in these references, or a different inventor. The Signature of Igor Shvets et al also does not have a letter "c" in it.

### *Claim Objections*

2. Claim 1 is objected to because of the following informalities: Claim 1 recites, "A biochip assembly (1) comprising…" and then further states, "characterized in that the biochip assembly (1) comprises:…." Claim 1 may be better worded if rewritten to state that the "biochip assembly (1) further comprises…" instead of, "characterized in that the biochip assembly (1) comprises:…." Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 3-5, & 8 are rejected under 35 U.S.C. 102(e) as being anticipated by SHVETS ET AL (WO03/060056).

5. The applied reference has both a common assignee and inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

6. Applicants’ claims are toward a device. Applicants’ claims contain "means" in describing limitations of the respective claims. The Examiner has interpreted the recited "means" in view of 35 U.S.C.112 6$^{th}$ Paragraph.

7. Regarding Claims 1, 3-5, & 8, SHVETS ET AL, discloses the biochip assembly (1) comprising (See Figure 1 Item 1; cell based assay assembly):

8. A). A plurality of enclosed elongate microchannels, each microchannel having an inlet port adjacent one of its proximal and distal ends; and an outlet port adjacent its other end (See Figure 2 Item 2; (Item 2 is shown in Figure 1 Item 1); Item 20, 21, 22, & 24 – biochip, microchannel, inlet port, and outlet port & Page 25 lines 19-23. Also See Figure 20 Item 20, microchannel module);

9. B). A plurality of reservoir wells for use with the microchannels (See Figure 2 Item 30 reservoir wells & Page 25 lines 23-26 & See Figure 20, Items 19);

10. C). An enclosed liquid delivery channel assembly having two or more combined inlet and outlet ports, at least one forming an inlet port and at least one other forming an outlet port (See Figure 2 Unit 3 or Items 17,18, 35, 36, & 37 & See Page 25 lines 30-33 & See Figure 20, most far left module);

11. D). An enclosed sample holder transfer assembly for connecting a port of one part of the biochip assembly to a port or reservoir well of another part and for connecting two reservoir wells together (See Figure 11 (Items 18, support plate; 40, tube; 41, rigid tube; 45, rigid tube; 46, support plate; & 49, interconnect tube. See Figure 8 Items are labeled in Figure 11 and correspond to components in Figure 8) characterised in that the biochip assembly (1) comprises:

12. E). A main support frame (See Figure 2 Item 15; planar sheet & See Figure 20 Item 12 is the face of the planar sheet 15);

13. F). A plurality of separate and removable biochip modules (See Figure 2 & Page 25 lines 19-30), namely an input module forming the enclosed liquid delivery assembly

(See Figure 2 Unit 3 or Items 17, 18, 35, 36, & 37 & See Page 25 lines 30-33 & See Figure 20; biochip modules);

14. G). At least one reservoir well containing a module (See Figure 2 Item 30 reservoir wells & Page 25 lines 23-26. See Figure 20 Items 19) and;

15. H). A microchannel containing module (See Figure 2 Item 2; – which is shown in Figure 1 Item 1; Item 20, 21, 22, & 24 – biochip, microchannel, inlet port, and outlet port & Page 25 lines 19-23 & See Figure 20 Item 20); and

16. I). In which the enclosed sample holder transfer assembly comprises a pair of support plates; a plurality of rigid tubes mounted on each support plate for engagement with the modules and with transfer conduits for connecting a rigid tube on one support plate with a rigid tube on the other support plate (See Figure 11 (Items 18, support plate; 40, tube; 41, tube; 45, rigid tubes; 46, support plate; & 49, interconnect tube & Figure 10 Items labeled as in Figure 11 (tubes, rigid tubes, and interconnect tubes labeled in Figure. Support plates are not labeled & See Figure 8, support plates are connected to rigid tubes and Item 40).

17. Additional Disclosures Included: Claim 3: There are two reservoir containing modules (See Figure 2 Items 19); Claim 4: A reservoir containing module (See Figure 2 Items 19) is arranged on either side of the microchannel containing module with the input module adjacent one of the reservoir containing modules (See Figure 2, Items 19 are on either side of the microchannel containing module (Item 20). Unit 3 (far most left module) is adjacent to one of the reservoir modules); Claim 5: Releasable connection means are provided on the main support frame for securing each of the support plates

in spaced-apart relationship with each of the input module and the microchannel containing module and with each rigid tube connecting in liquid sealing manner with the appropriate port (See Figure 25 Item 63; releasable connection means & Page 42 lines 20-27); and Claim 8: The cross-sectional area of the microchannel varies along its length (See Figure 20 Item 20).

***Claim Rejections - 35 USC § 103***

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

20. Determining the scope and contents of the prior art.
21. Ascertaining the differences between the prior art and the claims at issue.
22. Resolving the level of ordinary skill in the pertinent art.
23. Considering objective evidence present in the application indicating obviousness or nonobviousness.

24. Claims 2 & 9 are rejected under 35 U.S.C. 103(a) as being obvious over SHVETS ET AL (WO03/060056) in view of SHVETS ET AL (EP1252929).

25. The applied reference has a common inventors and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a)

might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

26. Applicants' claims are toward a device.

27. Regarding Claim 2, SHVETS ET AL discloses the biochip assembly as claimed in Claim 1, except wherein the transfer conduits are of a flexible material. SHVETS ET AL (EP1252929) discloses a biochip assembly wherein the transfer conduits are of a flexible material (See [0022]; plastic tubing is interpreted as flexible material). It would have been obvious to one or ordinary skill in the art at the time the invention was made to modify SHVETS ET AL (WO03/060056) with the flexible material of SHEVTS ET AL (EP1252929), because according to SHVETS ET AL (EP1252929), one of the great advantages of plastics material is that it enables real-time monitoring with relative ease, by use of a inverted microscope (See [0035]).

28. Regarding Claim 9, the combination of SHVETS ET AL and SHVETS ET AL disclose the biochip assembly as claimed in Claim 1, except wherein the particular embodiment as cited above discloses that the microchannel containing module comprises: sheets of flat plastics material laminated together to form an upper layer having through holes for forming input ports and output ports: an intermediate layer having cut-out through slots forming microchannels; and a base layer. It would have been obvious to one of ordinary skill in the art to modify the embodiment disclosed by the combination of SHVETS ET AL and SHVETS ET AL, because according to SHVET ET AL (WO03/060056), in another embodiment of the invention, the microchannels are all formed on one bottom face of a planar biochip sheet of translucent plastics material as open cutout channels covered by a thin film of polymer material coated with a pressure sensitive adhesive material, the other top face of the biochip sheet mounting the input ports, the output ports and the reservoir wells which microchannels may be non-cylindrical cross-section (See Page 17 lines 29-34 & Page 51 Claim 11); the fluidic connection ports, comprising eight connections in parallel are glued in position at the exit of the flow splitter, i.e. the main feeder channels 36, and at the input and output of the analysis section. A single connection port is glued at the input of the flow splitter to provide the liquid inlet port 37. Microwells for the preparation of the sample and collection after the analysis of said sample are introduced via similar hot embossing procedures using a specifically designed microwell-mould (See Page 44 lines 1-14); and because according to SHVETS ET AL (EP1252929), the biochips are fabricated using standard lithographic and hot embossing techniques. A stainless steel substrate is

masked with photoresist (SU-8-5 m, Chestech). After ultraviolet lithography, the photoresist mask is developed and the substrate is electrochemically etched to produce a negative master mould in stainless steel. The remaining mask is subsequently removed. Hot embossing is employed to replicate the microfluidic pattern of the microchannels in a variety of thermoplastic materials such as PMMA, polycarbonate, and polystyrene (See [0021]).

29. Claims 6 & 7 are rejected under 35 U.S.C. 103(a) as being obvious over SHVETS ET AL (WO03/060056) in view of Benett et al (US6273478).

30. Applicants' claims are toward a device. Applicants' claims contain "means" in describing limitations of the respective claims. The Examiner has interpreted the recited "means" in view of 35 U.S.C.112 6$^{th}$ Paragraph.

31. Regarding Claims 6 & 7, SHVETS ET AL discloses the biochip assembly as claimed in claim 5, except in which each port comprises a compressible seal for engagement with a rigid tube.

32. Benett et al discloses a biochip assembly in which each port comprises a compressible seal for engagement with a rigid tube (See Figure 1; Item 10, miniature fluid connector; Item 11, rigid tube; Item 13, elastomer seal (compressible seal); & Item 14 (microfabricated fluidic device is interpreted as a biochip assembly).

33. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the biochip assembly of SHVETS ET AL with the miniature fluid connector of Benett et al because the miniature fluid connector solves

the problem addressed by SHVETS ET AL of correctly matching parts during scaling down of components (See Page 7 lines 29-31) of the biochip assembly in order to avoid the accumulation of the sample at the place of their junction or at the input port and appearance of the air bubbles (See Page 7 lines 29-31), and because Benett et al explicitly discloses that the miniature fluid connector has many features, including ease of connect and disconnect; a small footprint which enables numerous connectors to be located in a small area; low dead volume; helium leak-tight; and tubing does not twist during connection. Thus the connector enables easy and effective change of microfluidic devices and introduction of different solutions in the devices (See Benett et al, Abstract).

34. Regarding Claim 7, SHVETS ET AL in combination with Benett et al discloses the biochip assembly as claimed in Claim 6, except in which the releasable connection means is adapted to engage the rigid tube with the compressible seal to form a liquid seal.

35. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the releasable connection means of SHVETS ET AL that is adapted to engage the rigid tube with the compressible seal to form a liquid seal with the miniature fluid connector of Benett et al because the miniature fluid connector solves the problem addressed by SHVETS ET AL, of correctly matching parts during scaling down of components (See Page 7 lines 29-31) of the biochip assembly in order to avoid the accumulation of the sample at the place of their junction or at the input port and appearance of the air bubbles (See Page 7 lines 29-31) because Benett et al

explicitly discloses that the miniature fluid connector has many features including ease of connect and disconnect; a small footprint which enables numerous connectors to be located in a small area; low dead volume; helium leak-tight; and tubing does not twist during connection. Thus the connector enables easy and effective change of microfluidic devices and introduction of different solutions in the devices (See Benett et al, Abstract).

36. Claims 10 & 11 are rejected under 35 U.S.C. 103(a) as being obvious over the combination of SHVETS ET AL (WO03/060056) and SHVETS ET AL (EP1252929), and in further view of LI ET AL (Journal of Micromechanics and Microengineering, June 20, 2003).

37. Applicants' claims are toward a device.

38. Regarding Claims 10 & 11, the combination of SHVETS ET AL and SHVETS ET AL disclose the biochip assembly as claimed in Claim 9, except wherein the intermediate layer is of a photo-resist fluoro-polymer material, secured to the other layers by ultraviolet (UV) curing.

39. Both SHVETS ET AL and SHVETS ET AL disclose that the biochip assembly is produced by using sheets plastics materials, of which SU-8-5, the negative photoresist is included (See SHVETS ET AL (WO03/060056; See Page 17 line 29 to Page 18 line 6) & See SHVETS ET AL (EP1252929; [0021]-[0022])

40. LI ET AL discloses a biochip assembly in which the intermediate later is of a photo-resist fluoro-polymer material, secured to the other layers by ultraviolet curing

(See Page 733, Section 2; Experiment Steps 1-6), Table 2, SU-8-5, and Figures 1 & 2). It would have been obvious to one or ordinary skill in the art at the time the invention was made to modify the biochip assembly of the combination of SHVETS ET AL and SHVETS ET AL, with the biochip processing of LI ET AL because according to the results of LI ET AL as shown in Table 2, the SU-8-5 material produces, "a clear almost clear status of the sealed device channels" which would benefit and coincide with SHVETS ET AL wanting to produce the biochip assembly out of a SU-8-5 negative photoresist and plastic material to enable real-time monitoring with relative ease by use of a inverted microscope (See SHVETS ET AL (EP1252929), [0035]).

41. Additional Disclosures Included: Claim 11: The intermediate layer is of a photo-resist fluoro-polymer material secured to the top layer by ultraviolet (UV) curing and the bottom layer is a peel-off sheet of polyester film, secured to the intermediate layer by an adhesive (See SHVETS ET AL (EP1252929); [0021] polyester film, permanent adhesive, polyester release liner).

***Telephonic Inquiries***

42. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BOBBY RAMDHANIE whose telephone number is (571)270-3240. The examiner can normally be reached on Mon-Fri 8-5 (Alt Fri off).

43. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

44. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

45. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bobby Ramdhanie/
Examiner, Art Unit 1797